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10/698,924	10/31/2003	K. Raja Reddy	45198.00047.UTL	2985

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/698,924

Applicant(s)

REDDY ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) 1-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 55-98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 1-98 are pending in this application.

Claims 1-54 are drawn to non-elected invention.

***Restriction Requirement***

The election of group II with traverse in Paper filed 5/2/05 is hereby acknowledged. The traversal is on the basis that formula V is within the scope of formula II. The Examiner is in total agreement with the applicant, and the invention of group III, claims 78-96, is now rejoined. Applicant also contends that since compounds of formula I are embraced by groups I, II and IV, and formula IV is within the scope of formula I, it would not be a burden on the Examiner to examine all the inventions of groups I-IV. This is not persuasive because groups I-II are drawn to compounds while groups III-IV are drawn to process of making. Election of a process of making is not subject to a rejoinder of the compounds thereof. See advisory of rejoinder in the last Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 57, 61, 67, 74, 78, 84, 92, 94, 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 recites "acyclic nucleoside." The term "acyclic" means straight chain nucleoside. There is no nucleoside known to be non-cyclic and the specification fails to provide an explicit definition for the term.

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The phraseology "selected from the group consisting of halogen" in claim 61, last line, renders the claim confusing and therefore indefinite. More than one group must follow the phraseology. By replacing the phraseology with "an halogen" the rejection would be overcome.

The abbreviations LDA, LHMDs, t-BuOK, DBU, DABCO, claim 67; MOM, MEM, claim 84; t-BuOK in claim 92 and DBU in claim 94 are not common chemical nomenclature, not known to the Examiner, and are not defined in the specification on first occurrence as required under standard scientific practice. By adding their full names the rejection would be overcome.

Substituent M in formulae IIA and B in claim 74 is not defined and therefore the claim is indefinite.

The phraseology "coupling a phosphorylating agent of formula IV and optionally protected cytarabine", claim 78, lines 4-5, is not clear and therefore the claim is indefinite. Is applicant coupling the agent with cytarabine or the agent and cytarabine with something else not yet identified in the claim? If the earlier is true "and" in the phraseology should be replaced with "with".

According to the invention, only oncolytic and antiviral agents having O, S or N through which to attach to P are applicable. Therefore, the structures of such agents must be provided in claim 97 for the Examiner to determine if and if not the agents are applicable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 55-60, 66-67, 74-79, 82-87, 97-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Erion et al., WO 99/45016.

Erion et al, disclose the instantly claimed process of making prodrugs by reacting the phosphorylating agent of formula I with MH in the presence of a base at pages 73-77. MH is nucleoside or any bioactive agent or drug. M is attached to P via O, C, N or S. See the entire document particularly, pages 54-55, 62-63, the examples and claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-60, 66-67, 74-79, 82-87, 97-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erion et al., WO 99/45016.

Applicant claims a process of making prodrugs by reacting the phosphorylating agent of formula I with MH in the presence of a base. In preferred embodiments, the phosphorylating agent has different nucleotides as substituents, which are optionally protected.

#### **Determination of the scope and content of the prior art (MPEP 2141.01)**

Erion et al, disclose the instantly claimed process of making prodrugs by reacting the phosphorylating agent of formula I with MH in the presence of a base at pages 73-77. See the entire document particularly, pages 54-55, 62-63, the examples and claims.

#### **Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)**

The difference between the instant invention and that of Erion et al., is that applicant is claiming phosphorylating agent having different nucleotides as substituents, which are optionally protected instead of no protection by Erion et al.

*Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)*

Different substituents of the phosphorylating agent which are optionally protected make the instant phosphorylating agent analogous to the phosphorylating agent of Erion et al., and using an analogous starting material in a well-known process is prima facie obvious. *In re Durden*, 226 USPQ 359 (1985). Therefore, the instant process is prima facie obvious from the teaching of Erion et al. One of ordinary skill in the art would have known to use analogous reagent at the time the invention was made. The motivation for using analogous nucleoside is from the teaching of Erion et al., that MH is any nucleoside, bioactive agent or drug.

***Double Patenting Rejection***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55-98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 83-91 of U.S. Patent No. 6,312,662.

Although the conflicting claims are not identical, they are not patentably distinct from each other

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because both set of claims are drawn to the same subject matter and the instantly claimed process is in the claims of US "662.

### ***Specification***

The specification is object to for having numerous abbreviations, which are not common chemical nomenclature and are not defined in the specification on first occurrence in accordance with the standard scientific practice.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD., JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**  
Group 1626

June 15, 2005